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IN THE

Supreme Court of the United States

PENNSYLVANIA EMPLOYEES BENEFIT TRUST FUND, ET AL.,

Petitioners,

v.

ZENECA, INC. ET AL.,

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN OPPOSITION

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QUESTION PRESENTED

Whether the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, and Food and Drug Administration ("FDA") regulations preempt state law false advertising claims when the marketing challenged in the complaint is based on FDA-approved labeling of a prescription drug.

PARTIES TO THE PROCEEDING

Petitioners Pennsylvania Employees Benefit Trust Fund ("PEBTF"), Joseph Macken, and Commissioner Linda A. Watters were plaintiffs in the district court and appellants in the court of appeals.

Respondents Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca")* were defendants in the district court and appellees in the Court of Appeals.

The petition's List of Parties to the Proceeding also identifies, as petitioners, AFSCME District Council AFSCME District Council 47 Health & Welfare Fund, Victoria Scofield, Janet McGrorty, Richard Tikkuri, Wisconsin Citizen Action, United Senior Action of Indiana, and North Carolina Fair Share. These parties were plaintiffs in the district court but failed to file a notice of appeal and were not included in the Notice of Appeal filed by PEBTF, Macken, and Watters. Accordingly, in the court of appeals, AstraZeneca moved pursuant Federal Rule of Appellate Procedure 3(c) to dismiss the appeal as to the seven non-appealing plaintiffs. The court of appeals denied the motion as moot due to the court's affirmance of the judgment. See Pet. App. 3a n.2. Nonetheless, because the failure to file a notice of appeal is jurisdictional, see *Airline Pilots Ass'n* v. *Cont'l Airlines (In re Cont'l Airlines)*, 125 F.3d 120, 128-29 (3d Cir. 1997) (citing *Torres* v. *Oakland*

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* Pursuant to Rule 29.6, respondents hereby state that AstraZeneca Pharmaceuticals LP and Zeneca Inc. are wholly-owned subsidiaries of AstraZeneca PLC. American Depository Receipts of AstraZeneca PLC are available on the New York Stock Exchange; no other publicly held corporation owns 10 percent or more of the stock of Zeneca Inc. or of AstraZeneca Pharmaceuticals LP.

Scavenger Co., 487 U.S. 312, 320-21 (1988)), AstraZeneca maintains that these entities are not parties in this Court.

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BRIEF IN OPPOSITION

Respondents Zeneca Inc. and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca") respectfully oppose the petition for writ of certiorari.

The conflict preemption principles that dispose of petitioners' claims are uncontroversial and even undisputed. Federal law preempts state law false advertising claims that challenge the promotion of a prescription drug based on FDA-approved labeling. Such preemption flows inevitably from the federal statutory and regulatory process for approving prescription drugs. Approval of labeling is an essential element of new drug approval, and FDA shall not approve labeling that is "false or misleading in any particular." 21 U.S.C. § 355(d). Once approved,

labeling serves as the basis for drug promotion. Any state law that makes it unlawful for manufacturers to promote drugs based on labeling that FDA has already determined is neither false nor misleading directly conflicts with and obstructs the federal scheme.

This is the basis on which the district court dismissed petitioners' Consolidated Class Action Complaint ("Complaint"). The district court held that petitioners' claims were preempted because all of the challenged promotional activity is supported by FDA-approved labeling. No decision of this or any other court conflicts with the preemption principle that the district court applied.

This legal principle is so straightforward that even petitioners have not challenged it. They have claimed that their Complaint challenges conduct beyond what the labeling supports. But that assertion raises a purely case-specific dispute about the breadth of their Complaint that does not warrant this Court's review. Furthermore, their assertion is belied by a simple comparison of the Complaint with the labeling. That comparison confirms that this Court's review would not extend beyond the straightforward rule of conflict preemption that petitioners do not dispute.

Petitioners also argue that the court of appeals affirmed the district court's judgment on a broader ground of field preemption, one that would render all state law false advertising claims preempted regardless of their relationship to FDA-approved labeling. That is neither what the court of appeals said it held nor what it needed to hold in order to affirm the judgment. Petitioners' broad reading of the opinion is in any event not in conflict with, and indeed has never even been addressed by, any other court. Thus, that broad reading would not merit this

Court's review even if the Court were likely to reach it, which it is not.

COUNTERSTATEMENT OF THE CASE

1. *Regulatory background.* Congress has regulated prescription drugs since 1906 with the Federal Food and Drugs Act and continuing through the present with the modern Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Congress has designated FDA as the "expert agency" for carrying out the FDCA's purposes and ensuring the safe and effective use of prescription drugs. *Weinberger* v. *Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). FDA's mission includes "promot[ing] the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products." 21 U.S.C. § 393(b)(1).

In connection with this mission, FDA has exclusive jurisdiction to evaluate a "new drug application" ("NDA"), the approval of which is necessary to market a drug in the United States. See *id.* § 355(a),(b); see also *Hynson*, 412 U.S. at 627. An NDA must include, among other information, (1) the clinical studies and reports showing that a drug is "safe" and "effective" for its proposed uses,[1] and (2) the proposed labeling (or "package insert"), which describes the drug's pharmacology and sets forth its uses and indications, approved dosage, adverse

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[1] See 21 U.S.C. § 355(b) (requiring that NDA include "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use"); 21 C.F.R. §§ 314.125(b)(2)-(5), 314.126.

events, and contraindications.[2] FDA reviews these materials and will approve an NDA only "after it determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling." 21 C.F.R. § 314.105(c). FDA shall not approve a drug if there "is a lack of substantial evidence that the drug product will have the effect it purports or is represented to have," or if its labeling is "false or misleading in any particular." 21 U.S.C. § 355(d); 21 C.F.R. § 314.125(b)(5),(6).

A prescription drug's labeling "communicates the conclusions of FDA review of the data" in the NDA and provides a key source for informing health care practitioners about the drug. Professional Product Labeling, 60 Fed. Reg. 52,196, 52,196 (Oct. 5, 1995). FDA "carefully controls the content of prescription drug labeling" to ensure that it "reflects thorough FDA review of the pertinent scientific evidence" and presents "the agency's formal, authoritative conclusions" about the drug's safe and effective use. Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922, 3968 (Jan. 24, 2006) ("Labeling Rule").

In recognition of FDA's expertise and its unique capacity to evaluate the accuracy of information presented to the public regarding prescription drugs, Congress has granted FDA the power to regulate prescription drug advertising. 21 U.S.C. § 352(n). Since 1985, FDA has permitted the promotion of prescription drugs not only to physicians but also

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[2] See 21 U.S.C. § 355(b); 21 C.F.R. § 314.50(c)(2)(i); see also 21 C.F.R. §§ 201.56-.57 (providing general and specific requirements, respectively, for prescription-drug labeling); *id.* § 201.80 (same for older drugs not subject to § 201.57).

directly to consumers. Direct-to-Consumer Promotion, 60 Fed. Reg. 42,581, 42,581-82 (Aug. 16, 1995).

FDA has adopted extensive and highly specific regulations to fulfill its obligation to prevent false or misleading prescription-drug advertising. See 21 C.F.R. § 202.1. FDA strictly regulates such activity through its Division of Drug Marketing, Advertising, and Communications ("DDMAC"), which oversees a "comprehensive surveillance, enforcement and education program." *Statement of Janet Woodcock Before the Senate Special Committee on Aging*, 2003 WL 21701807 (July 22, 2003). FDA's broad enforcement power includes the authority to seek injunctions, consent decrees, and seizures, to issue warning letters, and to make referrals for criminal prosecution. See 21 U.S.C. §§ 332, 333; see also Woodcock Statement, 2003 WL 21701807; Thomas A. Hayes, Drug Labeling and Promotion, 51 Food & Drug L.J. 57, 57-58 (1996). Congress recently heightened that power with the Food and Drug Administration Amendments Act of 2007 ("FDAAA"),[3] which, *inter alia*, authorizes the administrative imposition of civil monetary penalties for the dissemination of false or misleading DTC advertising. FDAAA § 901(d)(4), 121 Stat. at 940 (amending 21 U.S.C. § 333).

FDA also reviews advertising and promotional materials prior to approval and launch of any drug[4] and, post-launch, has required manufacturers to submit promotional labeling and advertising to

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[3] Pub. L. No. 110-85, 121 Stat. 823.

[4] See FDA, *Guidance for Industry: Formal Meetings With Sponsors and Applicants for PDUFA Products* 7 (Feb. 2000), http://www.fda.gov/cder/guidance/2125fnl.pdf.

DDMAC at the time of first use. 21 C.F.R. § 314.81(b)(3)(i). Under FDAAA, FDA now has the authority to require manufacturers to submit any prescription-drug television advertisement for review 45 days prior to its dissemination. See FDAAA § 901(d)(2), 121 Stat. at 939 (adding 21 U.S.C. § 353b).

The regulatory standards that ensure accuracy in information disseminated to the public through both labeling and advertising are intrinsically linked. See, *e.g.*, 21 U.S.C. § 352(n); 21 C.F.R. § 202.1(e)(3)(ii), (4), (6). Labeling "also serves as a basis for product promotion," and FDA regulations permit manufacturers to market approved drugs in accordance with FDA-approved labeling. Professional Product Labeling, 60 Fed. Reg. at 52,196 (explaining that a drug's advertising generally must "be consistent with its approved labeling"); see also 21 C.F.R. § 202.1(e); Labeling Rule, 71 Fed. Reg. at 3961 ("[Labeling] is often used to provide information for [DTC] advertisements."); Prescription Drug Advertising; Content and Format for Labeling of Human Prescription Drugs, 44 Fed. Reg. 37,434, 37,460 (June 26, 1979). For example, advertising claims about safety and efficacy, including comparisons to other drugs, must be based on what is "approved or permitted for use in labeling," or supported "by substantial evidence or substantial clinical experience," 21 C.F.R. § 202.1(e)(6)(i), just as "substantial evidence" must support claims in the labeling, *id.* § 201.56(a)(3). See also Hayes, *supra*, at 63.

In short, FDA labeling and advertising regulations operate together toward a common overarching goal: "to ensure that the promotion of medical products directed to professionals and consumers is truthful,

not misleading, and contains balanced risk and benefit information." Consumer-Directed Promotion of Regulated Medical Products, 70 Fed. Reg. 54,054, 54,056 (Sept. 13, 2005).

2. *Regulatory approval of Nexium.* Respondent AstraZeneca manufactures NEXIUM® (esomeprazole magnesium), which is one in a class of drugs called proton-pump inhibitors ("PPIs"). PPIs inhibit the production of stomach acid and are generally used to treat gastroesophageal reflux disease ("GERD" or "acid reflux disease"), which manifests in frequent heartburn, and erosive esophagitis ("EE"), which is damage to the lining of the esophagus. When, in February 2001, FDA issued its final approval to market Nexium, the final labeling stated it had been approved for three GERD-related indications: (1) healing of EE, (2) maintenance of healing EE, and (3) treatment of symptomatic GERD ("s-GERD"). See FDA, Nexium Label 24 (as approved Feb. 20 2001), http://www.fda.gov/cder/foi/label/2001/21153lbl.pdf ("Nexium Labeling").[5] AstraZeneca also manufactures and sells PRILOSEC® (omeprazole), which was the pioneer PPI.

Nexium's labeling summarizes the clinical studies used to obtain FDA approval. See Nexium Labeling at 10-15. For efficacy in treating EE, Nexium was tested at different doses—40 mg and 20 mg—and compared with omeprazole (Prilosec) at its maximum approved dose of 20 mg for EE healing. *Id.* at 10-11. AstraZeneca had similarly tested Prilosec at 40 mg and 20 mg doses for EE when seeking approval to

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[5] The FDA-approved labeling for both Nexium and Prilosec were placed before the district court (and similarly considered by the court of appeals) on an unopposed request for judicial notice.

market Prilosec, but FDA found that the "40 mg dose was not superior to the 20 mg dose of PRILOSEC in the percentage healing rate." FDA, Prilosec Label 11, http://www.fda.gov/cder/foi/label/2007/019810s085lbl.pdf ("Prilosec Labeling").

With Nexium, however, FDA reached a different conclusion. As Nexium's FDA-approved labeling shows, in all three clinical trials comparing Nexium 40 mg to omeprazole 20 mg, Nexium 40 mg showed higher rates of healing EE, and in two of these trials the increased rate was statistically significant. Nexium Labeling 10. The labeling also summarizes data showing that Nexium 40 mg provided statistically significant, increased rates of sustained symptom resolution for EE patients as compared to omeprazole 20 mg. *Id.* at 11. Nexium 40 mg also demonstrated faster resolution of symptoms for EE patients, as the labeling states: "In these four studies, the range of median days to the start of sustained resolution (defined as 7 consecutive days with no heartburn) was 5 days for NEXIUM 40 mg, 7-8 days for NEXIUM 20 mg and 7-9 days for omeprazole 20 mg." *Id.* Accordingly, the labeling reflects that FDA approved Nexium at doses of 20 mg or 40 mg once daily (for 4 to 8 weeks) for the healing of EE. Nexium Labeling 24.[6]

3. *Petitioners' claims.* The Complaint acknowledges both that the studies showed Nexium 40 mg has advantages over Prilosec 20 mg, and that FDA relied upon these studies in approving Nexium. Supp. App. 11-13 (Compl. ¶¶ 50, 58). Nonetheless, the Complaint asserts that those studies were "skewed" and

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[6] Nexium was approved at 20 mg for maintenance of healing of EE and for treatment of s-GERD in patients not suffering from EE. *Id.*

"slanted" because they compared different doses of the two drugs—that is, they compared Nexium 40 mg to Prilosec's maximum approved dosage of 20 mg for healing EE. *Id.* at 17, ¶ 11; *id.* at 17, ¶ 75. "To be fair and objective," the Complaint asserts, "AstraZeneca should have escalated the dose of Prilosec as well." *Id.* at 17, ¶ 75. By not doing so, respondents allegedly "misled" physicians "by the studies with unfair comparisons." *Id.* at 26, ¶ 104.

Petitioners rely on the views of an FDA medical officer who believed "there is no benefit" to increasing Nexium's dose from 20 mg to 40 mg for healing EE, and who thus recommended against approving Nexium at 40 mg for that indication. *Id.* at 18, ¶ 79. Even though FDA authoritatively rejected this recommendation and approved Nexium 40 mg for healing EE, the Complaint maintains that AstraZeneca deceptively marketed Nexium at 40 mg "despite there being no clinical reason to do so." *Id.* at 19, ¶ 80; see also *id.* at 61, ¶ 155(e) (alleging that AstraZeneca acted unlawfully by "suppressing and/or omitting that the recommended dose of Nexium was 20 mg").

In petitioners' view, the studies comparing Nexium and Prilosec show that Nexium is essentially the same as Prilosec and offers "no clinical improvements" or "any medical benefits not available from use of Prilosec." *Id.* at 4, ¶ 14. Petitioners thus allege that the "objective conclusion from these studies that should have been part of AstraZeneca's disclosures to doctors and the Class would have been to simply double the standard dose of Prilosec, allow generic competition," and forget about Nexium. *Id.* at 18, ¶ 77.

On this basis, petitioners challenge what they allege are unfounded claims of Nexium's "superiority"

over Prilosec in the marketing of Nexium. *E.g.*, Pet. 2, 9-11, 25-26. Petitioners took the opportunity to amend an earlier complaint after an initial motion to dismiss, and quoted four television ads and attached eleven print ads. Nevertheless, petitioners were unable to identify a single advertisement in which AstraZeneca expressly promoted Nexium as "superior" to Prilosec, let alone a factual comparative statement they could allege was false. See generally Supp. App. 28-54, ¶¶ 111-142). Only two of the television ads and five of the print ads use the word "Prilosec," and none expressly states that Nexium is more effective than Prilosec. Indeed, the Complaint alleges that "[b]y 2002, all references to Prilosec were deleted from Nexium television advertisements." *Id.* at 32, ¶ 122. In light of these facts, petitioners conceded in the court of appeals that "it is true that no print ad uses the ***word*** 'superior' when comparing Nexium and Prilosec." Pls.-Appellants' Reply Br. 2.

Instead, Petitioners attack virtually every aspect of every Nexium ad as conveying a misleading message of "superiority." According to the Complaint, this deceptive message arises from:

- AstraZeneca's "proudly introduc[ing]" Nexium, Supp. App. 38-43, ¶¶ 126-131; *id.* at 62-63, ¶ 155(o);
- the description of Nexium as "new," see, *e.g.*, *id.* at 2, ¶ 7; *id.* at 29-30, ¶¶ 114, 116-117;
- the description of the conditions for which Nexium is indicated, including that it is "possible" to relieve heartburn and heal erosions in the esophagus with Nexium, *id.* 28-29, ¶¶ 112-14; *id.* at 31-32, ¶¶ 118-21; *id.* at 44-45, ¶¶ 132-33;

- the color (purple) of the Nexium capsule, *id.*; and
- AstraZeneca's urging consumers to "talk to your doctor" about Nexium, *id.* at 29, ¶ 113; *id.* at 31, ¶¶ 119-20.

These promotional statements are, in petitioners' view, misleading claims of Nexium's "superiority" over Prilosec because they "fail to disclose that . . . AstraZeneca manufactures a far less expensive drug [Prilosec] that is equally as effective." *Id.* at 45-55, ¶¶ 131, 133, 135, 137, 139, 141, 143; see also *id.* at 29, ¶ 114 (attacking ad for "failing to mention that the exact same relief" is possible with Prilosec); *id.* at 32, ¶ 122 (alleging that AstraZeneca's DTC advertising after 2002 made "no mention of the fact [that] it also manufactured an equally effective drug"); *id.* at 39, ¶ 127 (calling it misleading to "'proudly introduce'" Nexium when Nexium is "simply the same basic drug with the same clinical benefits" as Prilosec).

The Complaint, on behalf of a putative nationwide class, alleges claims for violation of the Delaware Consumer Fraud Act ("DCFA"), Del. Code, tit. 6, § 2511, *et seq.*, violation of the consumer protection statutes of all 50 states, unjust enrichment, and negligent misrepresentation. The Complaint seeks relief including actual and punitive damages, restitution, and injunctive relief.

4. *The district court judgment.* The district court granted respondents' motion to dismiss. As relevant here, the district court agreed with respondents that petitioners' claims were preempted by the FDCA and FDA regulations.

The district court recognized that the "information included in the labeling of a new drug reflects a

determination by FDA that the information is not 'false or misleading.'" Pet. App. 52a, 57a. This determination created, in the district court's view, a safe harbor of protected marketing: "if the FDA labeling supports the statements made in advertising for an FDA-approved drug, the statements are not actionable." *Id.* at 52a. The court reviewed each allegedly false statement identified in the Complaint, and determined that each was truthful and supported by Nexium's FDA-approved labeling. *Id.* at 53a-56a. The court emphasized that it "did not find any explicit statements that Nexium was 'superior' to Prilosec" and further rejected Plaintiff's implied superiority claim based on the "consisten[cy]" between Nexium's labeling and the challenged marketing statements. *Id.* at 58a. In short, the district court dismissed petitioners' false advertising claims because the allegedly false and misleading statements were supported by Nexium's labeling.

5. *The court of appeals affirms.* The court of appeals agreed that federal law preempted petitioners' claims based on FDA's approval of Nexium and its labeling and the relationship between FDA labeling and advertising regulations.[7] From the outset, the court of appeals recognized that petitioners' claims depend on attacking the studies and drug comparison referenced in Nexium's

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[7] The district court's review of Nexium's labeling, the challenged advertisements, and FDA's labeling and advertising regulations led it to dismiss petitioners' DCFA claim both under the DCFA "safe harbor" provision, Del. Code, tit. 6, § 2513(b)(2), and alternatively on preemption grounds. Pet. App. 56a-57a. The court of appeals disagreed as to the state law ground for dismissal because it construed the safe harbor narrowly to apply based only on FTC regulations, not FDA regulations. *Id.* at 6a, 16a.

labeling, with the Complaint asserting that AstraZeneca "incorrectly represented that Nexium was superior to Prilosec" because "a dose of 40 mg is not needed in most patients and that a fair comparison of 20 mg of Nexium to 20 mg of Prilosec would not have proven Nexium to be superior." Pet. App. 4a.

The court then reviewed FDA's extensive regulation of both prescription drug labeling and advertising. Pet. App. 12a-14a, 18a-21a. The court emphasized the "essential affinity between advertising and labeling" in the FDCA and FDA regulations, explaining that "the rules ... govern[ing] labeling also form the basis for the advertising regulations." *Id.* at 26-27a. The court also canvassed basic principles of conflict preemption. It observed that preemption may arise out of the "confluence between congressional purpose and agency purpose," *id.* at 24a, and where state law claims "frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority," *id.* at 25a. The court thus recognized the potential for state law claims to "unnecessarily frustrate the FDCA's purpose and FDA regulations," given the "extensive and specific" agency involvement in prescription-drug advertising. *Id.* at 26a.

In light of these principles, and the nature of petitioners' claims, the court of appeals agreed that petitioners' claims are preempted. The court of appeals observed that the "strong[ ] case for preemption occurs when FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising." Pet. App. 26. This is so because "to the extent that the advertising statements regarding Nexium are consistent with statements used in the labeling approved by FDA,

FDA has determined they are not false or misleading." *Id.* at 13a. Moreover, "[a]lthough the FDA did not explicitly approve Zeneca's advertising, the FDA did approve Nexium's labeling, which included clinical studies that showed statistically significant healing rates for 40 mg of Nexium as compared to 20 mg of omeprazole." *Id.* at 20a n.9. Given that the court of appeals, like the district court, recognized that petitioners' claims were premised on their view that the studies and drug comparison included in Nexium's labeling were misleading; *id.* at 4a, 49a, 58a n.5, this is just such a "strong[ ] case," *id.* at 26a.

The court of appeals' extensive discussion of the labeling and advertising regulations led it to consider whether a complaint's claims "might be actionable" when they "are not supported by the labeling," but it ultimately recognized that "it need not decide this question now." Pet. App. 14a. The ultimate, operative principle in this case was straightforward: the purpose of the FDCA "would be frustrated if states were allowed to interpose consumer fraud laws that permitted plaintiffs to question the veracity of statements approved by FDA." *Id.* at 27a. That principle led the court of appeals to conclude that conflict preemption applied "in this setting" and to affirm the dismissal of "the plaintiffs' state consumer fraud claims." *Id.* at 28a.

Judge Cowen dissented. Because he viewed the labeling as insufficient to support the challenged advertising, he would not have found the claims preempted. See Pet. App. 35a-38a.

REASONS FOR DENYING THE PETITION

The premise of the petition is that the court of appeals held that *all* state law false advertising

claims involving prescription drugs are preempted. Pet. *i*, 2-3, 17, 23, 27, 30. This case does not present that issue. This is an ordinary conflict preemption case, and the conflict with federal law is stark. This putative nationwide class action alleges that introducing and marketing Nexium as an effective new PPI from the makers of Prilosec was inherently deceptive, that any promotion of Nexium necessarily conveyed a message of superiority, and that AstraZeneca's comparative testing of Nexium and Prilosec was skewed because it compared different doses of the two drugs. This lawsuit is irreconcilable with FDA's decision to approve Nexium as a new and effective drug, and to approve labeling that summarizes the results of the very studies comparing different doses of Nexium and Prilosec that petitioners attack as misleading. Petitioners' claims directly conflict with Congress's decision to give FDA exclusive authority to decide whether to approve a new drug for marketing, to determine what information goes on the labeling, and to make labeling the foundation of what a pharmaceutical company is permitted to use in promoting an approved drug. The Complaint cannot go forward without disrupting the detailed statutory and regulatory scheme that expressly permits advertising supported by labeling that FDA necessarily has found is neither false nor misleading in any particular. The dismissal of petitioners' claims is based on uncontroversial, indeed unchallenged, principles of conflict preemption.

The Third Circuit's decision nowhere mentions "field" preemption. Even reading the decision as petitioners do, this Court's review would remain unwarranted because no decision of any state high court or federal appellate court discusses federal

preemption of state false advertising claims by the federal scheme regulating prescription-drug labeling and advertising. There is thus no urgent need for this Court's review of this relatively unexplored issue. Instead, it would be prudent for this Court to allow other courts, including other panels in the Third Circuit, to give the decision below whatever effect they believe is appropriate as cases arise in the future before devoting resources to a legal issue that petitioners strain to present here. That would be especially prudent because the district court unambiguously concluded that all the challenged advertising was supported by the labeling. Pet. App. 53a-56a. If this Court were to agree, then it would not reach petitioners' issue because affirmance would remain appropriate on a narrow, undisputed, and controlling conflict preemption principle.

1. Conflict preemption precludes a state law false advertising claim that attacks statements supported by FDA-approved labeling. Such claims directly conflict with and obstruct the specific FDA regulations regarding labeling and advertising.

"[S]tate law is naturally preempted to the extent of any conflict with" federal law. *Crosby* v. *Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). Conflict preemption arises "when compliance with both federal and state regulations is a physical impossibility, or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hillsborough Cty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985) (internal quotation marks and citations omitted). "Federal regulations have no less pre-emptive effect than federal statutes. Where Congress has directed an administrator to exercise his discretion, his judgments are subject to judicial

review only to determine whether he has exceeded his statutory authority or acted arbitrarily." *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 153-54 (1982).

These principles of conflict preemption might well have been developed with the role of FDA in regulating the labeling and advertising of prescription drugs in mind. Congress has made clear that FDA is the "expert agency," *Hynson*, 412 U.S. at 627, with exclusive authority over new drug approval. FDA reviews the labeling in deciding whether to approve that drug for marketing in the United States. See Pet. App. 11a-13a, 18a; *supra* at 3-4. FDA cannot approve a drug unless it reaches a substantive conclusion that the statements and information in the labeling are neither false nor misleading. See 21 U.S.C. § 355(d); Pet. App. 13a (citing, *inter alia*, 21 U.S.C. § 352(a); 21 C.F.R. § 314.125(b)(6)). Recognizing FDA's expertise, Congress placed FDA in charge of regulating prescription drug advertising. 21 U.S.C. § 352(n). Because labeling "also serves as the basis for product promotion," Professional Product Labeling, 60 Fed. Reg. at 52,196, FDA regulations permit a drug sponsor to advertise its drug pursuant to FDA-approved labeling. See Pet. App. 26a; *supra* at 6-7. The court of appeals thus aptly described the FDA regulatory structure as reflecting the "essential affinity between advertising and labeling." Pet. App. 26a.

As the court of appeals acknowledged, a "strong[] case for preemption" occurs where "FDA-approved labeling is the basis for allegedly fraudulent representations made in prescription drug advertising." Pet. App. 26a. State court plaintiffs may not "question the veracity of statements approved by FDA." *Id.* at 27a. State law claims that would

penalize drugmakers for disseminating information that FDA has concluded should be made public (in the labeling) and has concluded is not "false or misleading in any particular," 21 C.F.R. § 201.56(a)(2), would stand as an obstacle to Congress's purposes and the advancement of federal policy. Indeed, FDA itself has so concluded: "State law conflicts with and stands as an obstacle to achievement of the full objectives and purposes of Federal law if it purports to preclude a firm from including in labeling or advertising a statement that is included in prescription drug labeling." Labeling Rule, 71 Fed. Reg. at 3935-36.

2. Petitioners do not challenge these fundamental legal principles. Indeed, in the court of appeals, petitioners acknowledged that they could not "request that AstraZeneca alter any part of Nexium's labeling or *labeling-dependent statements in Nexium advertisements*." Pls.-Appellants' Opening Br. 34 (emphasis added). Instead, their petition positions the Complaint as not implicating the preemptive effect of FDA's approval of Nexium. But this litigation has, from the outset, been about whether the Complaint runs afoul of a preemption rule so basic that petitioners have, as a formal matter, not disputed it.

The district court carefully analyzed the allegations in the Complaint and concluded that none of the specific promotional statements attacked in the Complaint goes beyond the labeling. Pet. App. 53a-56a. That view is amply supported by the record, and this Court certainly does not sit to repeat such case-specific tasks. Were the Court to grant review, however, determining whether the judgment could be affirmed on that narrow ground would be the first inquiry.

That case-specific issue would be resolved as the district court resolved it. Although petitioners claim to be attacking the promotion of Nexium as "superior" to Prilosec, their Complaint shows otherwise. *Supra* at 10-11. The petition itself cites only ¶¶ 116-17 of the Complaint as exemplifying misleading DTC advertising. Pet. 11. This is the advertisement to which those paragraphs refer:

> Thinking about Nexium, today's purple pill? Good. But don't just think about Nexium, talk to your doctor about it. Find out if Nexium is right for you. Nexium – it's today's purple pill.

Supp. App. 29, ¶ 115.

Petitioners' reliance on this allegation lays bare why conflict preemption forecloses their claims. This advertisement makes no actual representations of fact and merely encourages further inquiry about Nexium. Petitioners are thus contending that even the most straightforward promotion of Nexium is inherently misleading because it contains – at best – an implicit comparison of Nexium to Prilosec. See Supp. App. 2, ¶7 ("[W]hy market a product as 'new' if it were not somehow better than the prior version?"). That claim cannot be reconciled with a federal scheme that specifically permits such advertising, based on labeling that expressly compares Nexium to Prilosec, and expressly summarizes studies on the relative efficacy of Nexium and Prilosec that supported approval of Nexium at a 40 mg dose for healing EE.

Similarly, where the petition and Complaint identify factual advertising statements, those statements are supported by the labeling. For example, it is not false or misleading to say that "relief is possible with the purple pill called Nexium,"

Pet. 11, because the labeling clearly indicates that Nexium was approved for relieving symptoms associated with GERD and EE. Similarly, it cannot be false or misleading to describe Nexium as a "new" drug,[8] to call it "powerful" for patients with EE,[9] or to promote Nexium's "healing rates" by showing doctors the studies featured in the FDA-approved labeling.[10] *Id.* at 9-10.[11]

Petitioners only underscore that they seek to challenge agency action in pointing to their proffer that "'in negotiations between FDA and AstraZeneca regarding Nexium labeling, FDA stated that it would not approve any representations by AstraZeneca that Nexium is more effective than Prilosec.'" Pet. 3

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[8] FDA indisputably approved Nexium as a "new" PPI (Supp. App. at 2, ¶ 6) and FDA regulations expressly permit drugs to be promoted as "new" within six months of launch. FDA, DDMAC, *Frequently Asked Questions* (Nov. 7, 2006), *at* http://www.fda.gov/cder/ddmac/faqs.htm#new (FDA permits advertising drugs as "new" for six months after launch).

[9] 21 C.F.R. § 202.1(e)(3)(ii) (permitting promotion of drug efficacy based on single indication); Nexium Labeling at 10-11 (summarizing studies showing efficacy of Nexium in healing and resolving s-GERD for EE patients).

[10] Petitioners rely on a *Wall Street Journal* article as exemplifying deceptive detailing practices, but the article merely referred to showing the doctor "data comparing 40 mg. of Nexium to 20 mg. of Prilosec"—the very same data FDA considered and permitted for inclusion in the labeling. Supp. App. 17, ¶ 88.

[11] Petitioners have also attempted to rely, both in the district court and before this Court, on the language of the company's 2000 Annual Report. Pet. 9-10 (citing Compl. ¶ 89). There are no allegations, however, that the Annual Report—which was prepared prior to Nexium's approval by FDA—was ever used in marketing Nexium. The district court correctly disregarded statements in this report. Pet. App. 51a n.3.

(quoting Pet. App. 30a). This proffer is not different in kind from the Complaint's reliance on the medical reviewer's recommendation that the agency not approve a 40 mg dose of Nexium for healing EE because "'there is no benefit" to such a dose. Supp. App. 18, ¶ 79. FDA regulations make clear that pre-approval meetings and correspondence do "not constitute final administrative action." 21 C.F.R. § 10.65(a); see also *id.* § 10.85(k) (providing that statement "given by an FDA employee orally ... is an informal communication" that "does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed"). It is thus the labeling that reflects the "agency's formal, authoritative conclusions" arising out of the NDA process and provides the basis for product promotion. Labeling Rule, 71 Fed. Reg. at 3968; see also 21 C.F.R. § 202.1(e); Professional Product Labeling, 60 Fed. Reg. at 52,196.

The foregoing examples, though not exhaustive, suffice to show that petitioners do not really contest particular factual representations in advertising. Petitioners never identify any allegedly misleading aspect of the ads that would not be equally applicable to the labeling.

Rather, the complaint inherently challenges the federal statutory and regulatory scheme that granted FDA exclusive authority to review and approve the final labeling for Nexium, to permit promotion based on that labeling, to approve a 40 mg dose of Nexium for healing EE, and to rely upon comparative studies with Prilosec that petitioners believe are misleading. See Pet. App. 4a, 20a n.9; *id.* at 52a-56a. FDA expressly permits promotion based on studies summarized in labeling, and retains expansive power

to monitor and prevent false advertising. See 21 C.F.R. § 202.1(e)(3)(ii), (4), (6)(i); Labeling Rule, 71 Fed. Reg. at 3961; Professional Product Labeling, 60 Fed. Reg. at 52,196.[12] Petitioners nowhere allege that FDA issued warning letters against the Nexium promotion that referred to Prilosec. Their Complaint necessarily asks a jury, under the rubric of state law, to second-guess regulatory decisions (such as whether the comparative studies were "slanted" or "skewed") that federal law squarely commits to FDA. They have no plausible false advertising claim apart from their labeling-dependent challenge. *Cf. Bell Atl. Corp.* v. *Twombly*, 127 S. Ct. 1955, 1965-66 (2007) (explaining that, even under Rule 8, a complaint must provide "more than labels and conclusions," and "naked assertion[s]" that conduct was unlawful are insufficient to justify proceeding with expensive and burdensome class litigation).

3. The decision below does not conflict with any decision of this Court or any provision of the FDCA. Petitioners argue to the contrary only by ignoring the uncontroversial conflict preemption principle that supports dismissal of the Complaint. Instead, petitioners argue that the court of appeals held that all state false advertising claims involving prescription drugs are preempted, regardless of whether the challenged statements are supported by FDA-approved labeling, and that this is an error of

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[12] See also FDA, *Guidance for Industry: Clinical Studies Section of Labeling for Human Prescription Drug and Biological Products – Content and Format* 2 (Jan. 2006), *available at* http://www.fda.gov/CDER/GUIDANCE/5534fnl.pdf (clinical studies section of labeling describes "adequate and well-controlled" studies that provide "primary support for effectiveness" and "facilitate an understanding of how to use the drug safely and effectively").

exceptional importance, Pet. 2-3, 17, 23, 26-27. At best, petitioners' assertion that the court of appeals misapplied this Court's preemption decisions or misread the statute amounts to a call for error correction that this Court routinely rejects.

Under any reading, however, the decision below does not conflict with a decision of this Court. Petitioners' effort to create a conflict turns solely on the case-specific question whether their state law claims "are consistent with" the applicable federal regulations. Pet. 24. As discussed above, their claims are not "consistent with" the regulations; they directly conflict with the federal regulatory scheme.

The cases cited by petitioners, such as *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 869, 870 (2000), *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141 (1982), *Louisiana Public Service Commission* v. *FCC*, 476 U.S. 355 (1986), and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), all support the court of appeals' decision, which is why the court relied upon those decisions. *Geier* is analogous here because this Court held that state law claims that would have made it unlawful to fail to install an airbag in an automobile are preempted by a federal agency's decision to permit manufacturers to phase airbags in over time. 529 U.S. at 864-65, 874-85. Here, state law claims that attack promoting Nexium based on its labeling are preempted by the agency's decision to permit such promotion. As in *Geier*, this case involves the attempt to enforce state standards where state laws would "frustrate regulations that have been promulgated following a specific inquiry into a particular area of agency authority." Pet. App. 24a-25a. *Fidelity Federal* and *Louisiana Public Service* also stand for the proposition that "agency regulations are also a source

of preemptive law." Pet. App. 23a-25a. And the court of appeals properly cited *Buckman* as an example of a case where preemption was appropriate to preserve agency "flexibility ... to pursue 'difficult (and often competing) objectives.'" *Id.* at 25a (quoting *Buckman*, 531 U.S. at 349). Likewise, the court of appeals determined, "plaintiffs' claims against Zeneca under state consumer fraud laws" would frustrate federal purposes. *Id.* 26a.[13]

Petitioners beg the question when they assert that the decision below conflicts with *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005). Contrary to petitioners' suggestion, the dismissal of their claims does not rest "solely on the extent of FDA regulations." Pet. 22. Preemption is appropriate here because their claims would require a state court to second-guess FDA's expert judgments reflected in

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[13] Petitioners also argue in passing that the court's decision should be reviewed because 21 U.S.C. § 352(n) refers only to print or broadcast advertising and not oral representations by sales representatives. Pet. 21. In fact, the dismissal of the Complaint does not rest exclusively on § 352(n), but on the conflict between petitioners' claims and Nexium's labeling. In any event, FDA has asserted authority over oral representations. See, *e.g.*, Warning Letter to John C. Martin, Gilead Sciences, Inc. 1 (July 29, 2003), http://www.fda.gov/foi/warning_letters/archive/g4180d.pdf (issuing warning based on "oral representations made at Gilead's promotional exhibit booth"); *see also* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed Reg. 64,074, 64,075-76 (Dec. 3, 1997) (Congress intended broad construction of "advertisement" in FDCA, such that the terms includes information from drug sponsors (other than labeling) "intended to supplement or explain the product"). Because petitioners' allegations regarding oral representations are substantively no different from those attacking print and broadcast promotions, their oral misrepresentation claims are just as barred as their print misrepresentation claims.

Nexium's labeling. For the same reason, there is no conflict with *Hillsborough County*, which, like *Bates*, merely stands for the inapplicable proposition that extensive federal regulation, by itself, does not support field preemption. Pet. 22-23 (quoting 417 U.S. at 717-18). Further, *Hillsborough County* rejected conflict preemption in the context of that case because the putative obstacle to the accomplishment of federal objectives was deemed "speculative." 471 U.S. at 720. Here, for the reasons discussed above, the conflict between petitioners' claims and the federal regulatory scheme is not speculative, but clear, unavoidable, and at the heart of the case.

Petitioners' reliance on Section 202 of the Drug Amendments of 1962 is similarly unavailing. That provision states that the amendments shall not invalidate a provision of state law "unless there is a direct and positive conflict between such amendments and such provision of State law." Pub. L. No. 87-781, § 202, 76 Stat. 780, 793. Neither party cited Section 202 below. Its meaning is not at issue because respondents have always maintained that, under ordinary preemption principles, there is a conflict between petitioners' claims and federal law. A savings clause such as section 202 does "not *bar* the ordinary working of conflict pre-emption principles" and does "not foreclose ... the possibility that a federal [regulatory] standard will pre-empt a state common-law tort action." *Geier*, 529 U.S. at 869, 870. Certainly nothing in Section 202 would bar a finding of preemption when FDA-approved labeling is the basis of challenged advertising statements.[14]

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[14] Petitioners also criticize the court of appeals' reference to 21 U.S.C. § 337(a), which provides that "all ... proceedings for the

4. The decision below also does not conflict with any decision of a federal court of appeals or state court of last resort. First, petitioners do not suggest there is any conflict with the narrow ground for dismissing the Complaint—that all promotions they attack are supported by Nexium's FDA-approved labeling. Second, even construing the decision below broadly as petitioners do, petitioners cite to no appellate decision even discussing the "field" preemption of prescription-drug false advertising claims or the scope of preemption arising out of the "essential affinity" between FDA's labeling and advertising regulations. Pet. App. 26a.

In this respect, the case law regarding the preemption of prescription-drug false advertising claims stands in sharp contrast to that involving the preemption of prescription-drug failure-to-warn claims. Numerous courts have addressed failure-to-warn claims, but petitioners cite none addressing the scope of preemption of prescription-drug false advertising claims and few courts (and no other circuit courts) have addressed the issue. Moreover, no court has considered the scope of advertising

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enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." *See* Pet. 25. But the decision in no way rested upon that provision, which merely supports the broader, applicable point that the federal scheme provides FDA with extensive authority and discretion in enforcing the FDCA and, specifically, in ensuring a proper balance in the dissemination of information about prescription drugs. Pet. App. 28a; *cf.* 21 U.S.C. § 336 (providing that nothing in FDCA "shall be construed as requiring the Secretary to report for prosecution ... minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning"); 21 C.F.R. § 10.30 (allowing citizens to report alleged violations and to petition the agency to take regulatory or enforcement action).

preemption in light of the recent amendments to the FDCA. Given the dearth of consideration of the issue in the lower courts, as well as the uncertain impact of new legislation, plenary review now of the issue petitioners seek to present would at best be premature.

The relative paucity of case law on preemption in the advertising context also reflects the desire of state legislatures not to have consumer fraud laws invade this sphere of federal authority. Broad challenges to the promotion of prescription drugs have been rejected on state law grounds under various "safe harbor" provisions to state consumer fraud laws. Although the court of appeals construed Delaware's safe harbor narrowly as covering only conduct governed by FTC, not FDA, regulations (Pet. App. 15a-16a; *supra* note 7), the safe harbor provisions in other states are broader than Delaware's. For example, the Florida Deceptive and Unfair Trade Practices Act broadly exempts from its application any "act or practice required or specifically permitted by federal or state law." Fla. Stat. § 501.212(1). Such provisions have repeatedly provided an independent state law ground for dismissing claims either identical or comparable to those here.[15] For this reason as well, the issue on

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[15] Florida courts have rejected a virtually identical challenge to the advertising of Nexium under that state's safe harbor, on the ground that all of the challenged promotional statements were supported by Nexium's FDA-approved labeling, as well as on the preemption grounds discussed here. *Prohias* v. *AstraZeneca Pharms., L.P.*, 958 So. 2d 1054, 1056 (Fla. Dist. Ct. App.), *review denied*, 969 So. 2d 1014 (Fla. Nov. 7, 2007) (table). Likewise, the consumer protection law of Illinois contains a safe harbor that has been interpreted to bar a challenge to promotional statements comparing different dosages of two drugs that, even if not directly approved by FDA, are

which petitioners seek review is unlikely to recur with the frequency that would warrant this Court's review.

Petitioners rely on *Levine* v. *Wyeth*, --- A.2d ---, 2006 WL 3041078 (Vt. Oct. 27, 2006), which this Court has agreed to review. *Wyeth* v. *Levine*, 75 U.S.L.W. 3500, 76 U.S.L.W. 3391 (Jan. 18, 2008) (No. 06-1249). *Levine* is irrelevant to the field-preemption gloss that petitioners place on the decision below, because the manufacturer in *Levine* "concede[dly]" did not argue for field preemption. *Levine*, 2006 WL 3041078, ¶ 8. As shown below, *Levine* also is in accord with the principle of conflict preemption that is dispositive here. Perhaps for that reason, petitioners did not cite *Levine* below, either pursuant to Fed. R. App. P. 28(j), or in their petition for rehearing en banc.

Levine involves claims about inadequate safety warnings, not false advertising claims. The distinction is significant because the Vermont court's decision turned on its interpretation of a particular regulation applicable to product safety warnings. According to the Vermont Supreme Court, the "Changes Being Effected" ("CBE") regulation, 21 C.F.R. § 314.70(c), permitted Wyeth to change its labeling unilaterally to "'strengthen a ... warning'" or an "'instruction'" for "'safe use,'" thus leaving "leeway" for state law to determine whether Wyeth, in fact, should have changed its labeling. *Levine*, 2006

"sufficiently within what is authorized by federal law." *Bober* v. *Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001); see also *N.J. Citizen Action* v. *Schering-Plough Corp.*, 842 A.2d 174, 177 (N.J. Super. Ct. App. Div. 2003) (dismissing broad challenge to allegedly false, implicit message of efficacy in all Claritin advertising based on "compliance with FDA regulations including regulations relating to DTC marketing campaigns").

WL 3041078, ¶¶ 12-14 (quoting § 314.70(c)); see also *id.* ¶ 22 (no conflict because "defendant was free under ¶ 314.70(c) to strengthen the warning without prior FDA approval"). Though crucial to the decision in *Levine*, the CBE regulation is inapplicable here, because petitioners brought only false advertising claims involving drug efficacy, and did not challenge the safety warnings in the labeling.

The Vermont Supreme Court also accepted the principle that state law may not be used to second-guess FDA's expert judgment; it rejected conflict preemption because it concluded that FDA never addressed the warning at issue. *Levine*, 2006 WL 3041078, ¶ 23. Here, by contrast, petitioners attack precisely what the labeling shows FDA did approve as the basis for the promotion of Nexium, namely, the results of comparative efficacy studies of different dosages of Nexium and Prilosec, and a 40 mg dose of Nexium for healing EE. Because the core principle of conflict preemption that is dispositive here was accepted in *Levine*, *id.*, and because the CBE regulation is inapplicable here, *Levine* provides no basis to grant or hold the petition.[16]

The decision below also does not conflict with *Perez* v. *Wyeth Laboratories, Inc.*, 734 A.2d 1245 (N.J. 1999). *Perez* addresses state law standards for duty-to-warn claims, principally focusing on whether the learned intermediary doctrine applied to DTC

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[16] The same is true of the other FDA-preemption case pending before the Court. *Warner-Lambert Co.* v. *Kent*, No. 06-1498 (set for argument Feb. 25, 2008), involves federal preemption of state law claims that depend on challenges to the adequacy of disclosures to FDA during the drug approval process; in the district court, petitioners disavowed any claim that AstraZeneca committed a fraud on FDA in obtaining approval for Nexium.

advertising as a matter of state law. See *id.* at 1246-47. It nowhere discusses preemption.

The other lower court decisions cited over the final pages of the petition reflect more of the same. Petitioners cite numerous cases for the proposition that no court has found the preemption of *all* prescription-drug false advertising claims. See Pet. 30-31. Not only is that not the operative principle of the decision below, but the cited cases do not address the question as petitioners frame it. Indeed, petitioners cite no case that considers, let alone attempts to define, the furthest boundaries of conflict preemption in the area of prescription drug advertising, other than the decision below (as petitioners read it).[17] Petitioners' reliance on various cases interpreting the phrase "direct and positive conflict" in different statutory schemes, Pet. 32-34, is also inapposite because the meaning of the phrase "direct and positive conflict" in § 202 of the 1962 Drug Amendments is not at issue, much less the meaning of that phrase in other statutes.

There is ample support for the dismissal of petitioners' claims on the undisputed preemption principle that petitioners may not challenge labeling-dependent statements in Nexium advertising.

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[17] Indeed, certain of the cases actually confirm the primacy of FDA's labeling decisions by emphasizing that the claims challenged advertising *contrary* to FDA-approved labels. *In re Warfarin Sodium Antitrust Litg.*, 391 F.3d 516, 521-23 (3d Cir. 2004) (claim that defendant falsely promoted its brand-name drug as superior to the generic version, which FDA had approved as therapeutically equivalent); *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 939-40 (8th Cir. 2005) (Lanham Act claims alleging that the defendant advertised its animal feed as having an approved use that FDA had not in fact approved).

Preemption has arisen infrequently in this context; should it arise in the future, other courts need not read the court of appeals' decision as broadly as petitioners do. The availability of a narrow, straightforward basis of affirmance would inhibit this Court's ability even to consider the field-preemption rule petitioners ascribe to the opinion below. Review in this case would be as imprudent as it is unwarranted.

CONCLUSION

The petition for writ of certiorari should be denied.

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